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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,907	02/17/2004	Robert D. Black	9099-18	8994

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EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,907	BLACK ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88,105 and 106* is/are pending in the application.

4a) Of the above claim(s) *1-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-88,105 and 106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/16/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/20/04 and 3/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention III in the reply filed on 12/15/2006 is acknowledged. There were no arguments presented regarding the grounds of the traversal. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL. Claims 1 – 88, 105, and 106 are pending, of which claims 1 – 42 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 43 – 88, 105, and 106 are readable upon the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 82 and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to "A ~~sensor~~ according to claim 70," and as such the claim is indefinite because it is unclear what is being claimed. It is interpreted for examination purposes that the term "sensor" was intended to be amended to read a "system," as recited in previous claims. Appropriate correction is requested.

Claims 70 – 76, 78 – 88, and 106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a system wherein the sensor is configured to be intermittently operated at plurality of sampling intervals over a monitoring period of interest. The claims are indefinite because the monitoring period during which sampling is to occur is unspecified and it is unclear what is encompassed by a period of interest. As such, the metes and bounds of the claims are not clearly set forth and the scope of the invention cannot be distinctly ascertained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 44, 46, 47, 54, and 105 are rejected under 35 U.S.C. 102(e) as being anticipated by Shults *et al.* (US 2004/0011671).

Shults discloses implantable devices and methods for determining analyte levels (abstract). The device comprises a housing including an electrical circuit, a sensor operably connected to the electronic circuit of the housing. The analyte levels may be measured for a time period exceeding 360 days (paragraphs 0009 – 0010). The implanted device may be radiotelemetrically operated, whereby data recorded by the device is transmitted to an ex vivo recording station (e.g. a computer), where data is recorded and further processed (paragraph 0027). A fluorescence sensor may be incorporated into the implantable device. The fluorescence sensor requires a source of light to detect the presence of an analyte (paragraph 0057). The device is cylindrical (paragraph 0067). The devices are implanted subcutaneously, which is inherently within the claimed range of up to (i.e. less than) 25 cm (paragraph 0119).

Claims 43 – 45, 54 – 56, 59 – 63, 65 – 69 and 105 are rejected under 35 U.S.C. 102(b) as being anticipated by Colvin *et al.* (US 6,330, 464).

Colvin discloses an optical-based sensor for detecting the presence or amount of an analyte (abstract). The sensing device is smooth and rounded and elliptical in shape and is an extraordinarily compact size which permits the device to be implanted in humans for in situ detection of various anlaytes (column 1, lines 11 – 21). Radiation (light) emitted from a source strikes and causes an indicator to fluoresce. A high-pass filter allows fluorescent light emitted by the indicator molecules to reach the photodetector while filtering out scattered light from the light source (column 1, lines 26 – 40). The sensor is self-contained with a source of radiation (such as an LED), and a

photosensitive element (such as a photodetector) (column 2, lines 16 – 20). The source of radiation may be powered by external means, and an inductor may be used to transmit information-bearing electromagnetic waves (column 2, lines 40 – 55). The sensor may be used subcutaneously in a human being (column 2, line 57). The diameter of the capsule may be 300 microns to approximately 0.3 inches (column 8, lines 13 – 25). The device may be telemetrically operated (column 10, lines 13 – 60) and may include means for signal transduction via radiofrequency or passive inductive telemetry to an external reader (i.e. processor) (column 26, lines 59 – 60). The capsule may be made of glass and epoxy (column 26, line 43 and column 23, lines 1 – 40). The device may include apertures and filters (column 23, lines 21 and column 22, line 27). A plurality of radiation sources may be used (column 24), and the LEDs can be activated for a fraction of a second, with one LED remaining off while the other is on (i.e. pulsed), and separate readings can be made due to temporal differences in emission (colum 25 lines 10 – 20). The detectors can detect radiation at the top and bottom sides (colum 35, lines 22 – 26). The detectors may be photoresistive, photodiodes, etc. and may include filters to separate excitation radiation from fluorescent emission radiation (column 36, lines 1 – 26).

Claims 43 – 45, 54 – 56, 59 – 61 and 105 are rejected under 35 U.S.C. 102(e) as being anticipated by Lesho *et al.* (US 2004/0054385).

Lesho discloses an implantable fluorescence sensor for detecting the concentration or presence of an analyte in the human body (paragraph 0002). The device optoelectrons circuitry, an RF oscillator, etc. for retrieving information from the sensor device and a processor for receiving and processing information signals (paragraphs 0007 – 0019). The sensor body is a biologically compatible optically trasmissive material which allows radiation generated by a source (i.e. an LED) to travel through it (paragraph 0043). The device contains filters (paragraph 0046 – 0047). The sensor is smooth and may be oblong in shape (paragraph 0050). The size is from 300 – 500 microns to 0.5 inches in length (paragraph 0050). The device comprises a photodiode detector, and light intensity may be pulsed with a 50% duty cycle (paragraph 0074).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 43, 44, 46, 47, 51, 52 – 55, 60, 61, 69 – 71, 73, 75 – 77, 85, 88, 105, and 106 are rejected under 35 U.S.C. 103(a) as being obvious over Shults *et al.* (US 2004/0011671) in view of Stavridi *et al.* (US 5,341,805).

Shults discloses implantable devices and methods for determining analyte levels (abstract). The device comprises a housing including an electrical circuit, a sensor operably connected to the electronic circuit of the housing. The analyte levels may be measured for a time period exceeding 360 days (paragraphs 0009 – 0010). The implanted device may be radiotelemetrically operated, whereby data recorded by the device is transmitted to an ex vivo recording station (e.g. a computer), where data is recorded and further processed (paragraph 0027). A fluorescence sensor may be incorporated into the implantable device. The fluorescence sensor requires a source of light to detect the presence of an analyte, such as glucose (paragraph 0057). The device is cylindrical (paragraph 0067). The devices are implanted subcutaneously, which is inherently within the claimed range of up to (i.e. less than) 25 cm (paragraph 0119).

Shults fails to specifically recite that the excitation light is generated by a laser diode of a specific intensity and that the device comprises a detector including a filter.

Stavridi teaches a glucose monitor that monitors glucose concentration by monitoring fluorescent light produced directly by any glucose present in a sample. The monitor may be in the form of a probe which may be adapted to percutaneously monitor

the concentration of glucose in the body through the skin (column 2, lines 48 – 50). The monitor includes a light source, a sensor, and a processor. The light source is an excitation light which emits light having wavelengths from 250 – 350 nm and 380 to 420 nm (column 1, line 50 – column 2, line 9). One spectral peak observed (i.e. detected) occurs at 440 nm (column 4, line 29). The excitation light can be produced from a diode laser (column 3, line 68), and the intensity of the light should be from one millijoule per square millimeter to 15 millijoule per square millimeter (column 4, lines 1 – 7). Regarding claim 51, it is noted that Stavridi does not specifically recite that the light penetrates tissue that is up to 20 mm away, however it is interpreted, in the absence of evidence to the contrary, that the laser diode of Stavridi, which is operated at an intensity within the claimed range, would inherently have this capability. Furthermore, it is noted that there is no lower limit regarding the distance that light should penetrate, and as such even a very small amount of tissue penetration would meet the limitation of the claim (i.e. light which penetrates a tissue at a distance of less than 20 mm). The system includes a detector, including a second detector, which includes a light-sensitive diode with band-width filters (column 4, lines 8 – 20).

Stavridi fails to teach that the monitoring system is telemetrically operated, or that the percutaneous monitoring occurs over an extended period of time.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the fluorescence sensor, including the excitation light source and detector such as that taught by Stavridi, in the telemetrically operated sensor device of Shults, which is implanted and used to detect analyte levels over a

long period of time. One would have been motivated to do so and would have had a reasonable expectation of success in doing so because Shults teaches their device to be an improvement over the monitoring system of Stavridi because their device is better suited to survive harsh in vivo environmental conditions and functional integration into body tissues (paragraph 0056).

Claims 43 – 47, 51 – 88, 105, and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin *et al.* (US 6,330, 464) in view of Shults *et al.* (US 2004/0011671) and Stavridi *et al.* (US 5,341,805), in further view of Lesho (US 2004/0054385).

Colvin discloses an optical-based sensor for detecting the presence or amount of an analyte (abstract). The sensing device is smooth and rounded and elliptical in shape and is an extraordinarily compact size which permits the device to be implanted in humans for in situ detection of various anlaytes (column 1, lines 11 – 21). Radiation (light) emitted from a source strikes and causes an indicator to fluoresce. A high-pass filter allows fluorescent light emitted by the indicator molecules to reach the photodetector while filtering out scattered light from the light source (column 1, lines 26 – 40), as set forth above.

Colvin fails to specifically recite the power at which the excitation light source is operated or the width of the dector in relation to the sensor body.

Shults discloses implantable devices and methods for determining analyte levels (abstract). The device comprises a housing including an electrical circuit, a sensor operably connected to the electronic circuit of the housing. The analyte levels may be measured for a time period exceeding 360 days (paragraphs 0009 - 0010). The implanted device may be radiotelemetrically operated, whereby data recorded by the device is transmitted to an ex vivo recording station (e.g. a computer), where data is recorded and further processed (paragraph 0027). A fluorescence sensor may be incorporated into the implantable device. The fluorescence sensor requires a source of light to detect the presence of an analyte, such as glucose (paragraph 0057). The device is cylindrical (paragraph 0067). The devices are implanted subcutaneously, which is inherently within the claimed range of up to (i.e. less than) 25 cm (paragraph 0119).

Shults fails to specifically recite that the excitation light is generated by a laser diode of a specific intensity and that the device comprises a detector including a filter.

Stavridi teaches a glucose monitor that monitors glucose concentration by monitoring fluorescent light produced directly by any glucose present in a sample. The monitor may be in the form of a probe which may be adapted to percutaneously monitor the concentration of glucose in the body through the skin (column 2, lines 48 - 50). The monitor includes a light source, a sensor, and a processor. The light source is an excitation light which emits light having wavelengths from 250 - 350 nm and 380 to 420 nm (column 1, line 50 - column 2, line 9). One spectral peak observed (i.e. detected) occurs at 440 nm (column 4, line 29). The excitation light can be produced from a diode

laser (column 3, line 68), and the intensity of the light should be from one millijoule per square millimeter to 15 millijoule per square millimeter (column 4, lines 1 - 7).

Regarding claim 51, it is noted that Stavridi does not specifically recite that the light penetrates tissue that is up to 20 mm away, however it is interpreted, in the absence of evidence to the contrary, that the laser diode of Stavridi, which is operated at an intensity within the claimed range, would inherently have this capability. Furthermore, it is noted that there is no lower limit regarding the distance that light should penetrate, and as such even a very small amount of tissue penetration would meet the limitation of the claim (i.e. light which penetrates a tissue at a distance of less than 20 mm). The system includes a detector, including a second detector, which includes a light-sensitive diode with band-width filters (column 4, lines 8 - 20).

Stavridi fails to teach that the monitoring system is telemetrically operated, or that the percutaneous monitoring occurs over an extended period of time.

Lesho discloses an implantable fluorescence sensor for detecting the concentration or presence of an analyte in the human body (paragraph 0002). The device optoelectrons circuitry, an RF oscillator, etc. for retrieving information from the sensor device and a processor for receiving and processing information signals (paragraphs 0007 – 0019). The sensor body is a biologically compatible optically trasmissive material which allows radiation generated by a source (i.e. an LED) to travel through it (paragraph 0043). The device contains filters (paragraph 0046 – 0047). The sensor is smooth and may be oblong in shape (paragraph 0050). The size is from 300 – 500 microns to 0.5 inches in length (paragraph 0050). The device comprises a

photodiode detector, and light intensity may be pulsed with a 50% duty cycle (paragraph 0074).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention that the power of the light source in the fluorescence sensor device taught by Colvin would be operated at an intensity from one millijoule per square millimeter to 15 millijoule, because emission light of such intensity has been shown in the art to be effective for in vivo fluorescence detection, as shown by Stavridi and Shults, both of which are directed to implantable devices for fluorescence detection of analytes in vivo. One would have been motivated to do so because Stavridi teaches that if the intensity is too low, obtaining a sufficient signal is difficult, whereas if the intensity is too high, sample ablation can occur. Regarding the limitations of claim 64 and 37, it is noted that Colvin does not specifically recite the size of the detector in comparison to the width of the sensor body and pulse operation. However, it is interpreted that factors such as the size and positioning of detector within the sensor body and the pulse are elements of the design of the sensor which may be variable without departing from the scope of the invention of Colvin, as Colvin discloses the presence of a photodiode detector within the sensor body, as well as pulsed operation of the light sources. Lesho is included to further demonstrate an implantable fluorescence sensor with a pulsed emission. It would have been obvious to vary the duty cycle of a pulsed because Lesho teaches that changes in duty cycle of the squarewave in determining analyte concentration are generally known in the art (paragraph 0074). It would have been obvious to one of ordinary skill in the art at the

time of the instant invention to incorporate the fluorescence sensor, including the excitation light source and detector such as that taught by Stavridi, in the telemetrically operated sensor device of Shults, Colvin, or Lesho, which is implanted and used to detect analyte levels over a long period of time. One would have been motivated to do so and would have had a reasonable expectation of success in doing so because Shults teaches their device to be an improvement over the monitoring system of Stavridi because their device is better suited to survive harsh in vivo environmental conditions and functional integration into body tissues (paragraph 0056).

Claims 43, 44, 46 – 55, 60, 61, 69 – 71, 73, 75 – 77, 85, 88, 105, and 106 are rejected under 35 U.S.C. 103(a) as being obvious over Shults *et al.* (US 2004/0011671) in view of Stavridi *et al.* (US 5,341,805), in view of Mayinger (*Am. J. Gastroent.*, 2001, 9, p. 2616 – 2621).

Shults discloses implantable devices and methods for determining analyte levels (abstract). The device comprises a housing including an electrical circuit, a sensor operably connected to the electronic circuit of the housing. The analyte levels may be measured for a time period exceeding 360 days (paragraphs 0009 – 0010). The implanted device may be radiotelemetrically operated, whereby data recorded by the device is transmitted to an ex vivo recording station (e.g. a computer), where data is recorded and further processed (paragraph 0027). A fluorescence sensor may be incorporated into the implantable device. The fluorescence sensor requires a source of light to detect the presence of an analyte, such as glucose (paragraph 0057). The

device is cylindrical (paragraph 0067). The devices are implanted subcutaneously, which is inherently within the claimed range of up to (i.e. less than) 25 cm (paragraph 0119).

Shults fails to specifically recite that the excitation light is generated by a laser diode of a specific intensity and that the devices are used to differentiate between normal and diseased tissue.

Stavridi teaches a glucose monitor that monitors glucose concentration by monitoring fluorescent light produced directly by any glucose present in a sample. The monitor may be in the form of a probe which may be adapted to percutaneously monitor the concentration of glucose in the body through the skin (column 2, lines 48 – 50). The monitor includes a light source, a sensor, and a processor. The light source is an excitation light which emits light having wavelengths from 250 – 350 nm and 380 to 420 nm (column 1, line 50 – column 2, line 9). One spectral peak observed (i.e. detected) occurs at 440 nm (column 4, line 29). The excitation light can be produced from a diode laser (column 3, line 68), and the intensity of the light should be from one millijoule per square millimeter to 15 millijoule per square millimeter (column 4, lines 1 – 7). Regarding claim 51, it is noted that Stavridi does not specifically recite that the light penetrates tissue that is up to 20 mm away, however it is interpreted, in the absence of evidence to the contrary, that the laser diode of Stavridi, which is operated at an intensity within the claimed range, would inherently have this capability. Furthermore, it is noted that there is no lower limit regarding the distance that light should penetrate, and as such even a very small amount of tissue penetration would meet the limitation of

the claim (i.e. light which penetrates a tissue at a distance of less than 20 mm). The system includes a detector, including a second detector, which includes a light-sensitive diode with band-width filters (column 4, lines 8 – 20).

Stavridi fails to teach that the monitoring system is telemetrically operated, or that the percutaneous monitoring occurs over an extended period of time.

Mayinger discloses fluorescence spectroscopy for the in vivo differentiation of normal and neoplastic human tissue using light from a xenon arc lamp and an optical probe comprising glass fibers (pages 2616 – 2617). Mayinger does not disclose an implantable fluorescence detection device.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the fluorescence sensor, including the excitation light source and detector such as that taught by Stavridi, in the telemetrically operated sensor device of Shults, which is implanted and used to detect analyte levels over a long period of time. One would have been motivated to do so and would have had a reasonable expectation of success in doing so because Shults teaches their device to be an improvement over the monitoring system of Stavridi because their device is better suited to survive harsh in vivo environmental conditions and functional integration into body tissues (paragraph 0056). It would have been further utilize implantable fluroescence sensors comprising a light source and configured to a processor, as taught by Shults, for the in vivo detection of cancer because Mayinger discloses that in vivo fluorescence measurements have been utilized for such purposes in the art. One would

have been motivated to utilize such implantable sensors, because Shults teaches the devices to have advantages such as long-term monitoring capability.

Conclusions

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER